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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/813,745	03/31/2004	Mathai Mammen	P-162-US1	5848

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EXAMINER	
BALLS, ROBERT J	

ART UNIT	PAPER NUMBER
1625	

DATE MAILED: 09/29/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/813,745	MAMMEN ET AL.	
	Examiner	Art Unit	
	R. James Balls	1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 February 2006*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-40* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-40* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1-40 are pending.

2. This application claims benefit of Provision Application Serial No. 60/459,291, filed on April 1, 2003.

3. Claims 1-40 are subject to election/restriction.

Election/Restrictions

4. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claim 19, drawn to compounds of formula III, classified in class 546, subclass 155. An election of a single disclosed species is required.

II. Claim 20, drawn to compounds of formula IV, classified in class 548, subclass 566. An election of a single disclosed species is required.

III. Claims 1-18 and 21-31 and 38- 40 (less the compounds of Claims 19-20) classified in various classes and subclasses depending on the particular species. Further restriction may apply to this group. An election of a single disclosed species is required.

IV. Claim 32 drawn to a composition comprising a compound from Groups I-III, further comprising a steroidal anti-inflammatory agent classified according to the individual species and/or additional therapeutic agent. An election of a single disclosed compound from Groups I-III, (from which restriction will according to Groups I-III) and an election of a single disclosed steroidal anti-inflammatory agent is required.

V. Claim 33 drawn to a composition comprising a compound from Groups I-III, further comprising a PDE4 inhibitor classified according to the individual species and/or additional therapeutic agent. An election of a single disclosed compound from Groups I-III, (from which restriction will apply according to Groups I-III) and an election of a single disclosed steroidal anti-inflammatory agent is required.

VI. Claim 34-36 drawn to a method of treating pulmonary disorders, providing bronchodialation or treating COPD and asthma classified in class 514, subclasses 312, 386+. An election of a single disclosed compound from

Groups I-III, (from which restriction will apply according to Groups I-III) is required.

VII. Claim 37 drawn to a method of studying a biological system or sample comprising a muscarinic receptor or a B2 adrenergic receptor classified in class 435, subclass 503. An election of a single disclosed compound from Groups I-III, (from which restriction will apply according to Groups I-III) is required.

Claims 1-18 and 21-31 and 40 links Groups I-III. The restriction requirement of the linked inventions is **subject to** the nonallowance of the linking claims, claims 1-18 and 21-31 and 40. Upon the indication of allowability of the linking claims, the restriction requirement as to the linked inventions **shall** be withdrawn and any claims depending from or otherwise requiring all the limitations of the allowable linking claims will be rejoined and fully examined for patentability in accordance with 37 CFR 1.104 **Claims that require all the limitations of an allowable linking claim** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

Applicant(s) are advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, the allowable linking claim, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

The inventions are distinct, each from the other because of the following reasons:

Groups I-III are inventions having independent and distinct chemical structures, which lack a substantial structural feature recognized in the art as being essential to the disclosed utility as evidences by their different classification. A reference that anticipates any one group of invention would not render another group obvious. Furthermore, in terms of searching, each group would require a different search, as the groups are not coextensive with each other. Therefore, searching the entire scope of the claims without restriction would pose a tremendous burden on the office.

Should applicants traverse on the ground that the groups are not patentably distinct, applicants should submit evidence or identify such evidence now of record, i.e. show that the compounds of Groups I-III are obvious variants of one another or clearly admit such on the record. Thus, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission that the groups are not patentably distinct may be used in a rejection under 35 U.S.C. §103(a) against the other groups.

Group XI is related to Groups I-III as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using theat product. See MPEP 806.05(h). In the instant case, each method can be practices with a materially different product. For example, U.S. Patent No. 4,250,188 provides compounds capable of treating pulmonary disorders.

Groups IV and V are related to Groups I-III in that Groups IV and V contain a compound of Groups I-III. Inventions IV and V are each independently patentably distinct from Inventions I-III and between each other due to the added element of an additional therapeutic agent. For instance, a reference that anticipates Groups I-III would not necessarily render a composition comprising the anticipated compound(s) with an additional therapeutic unpatentable. Furthermore, a search of Inventions I-III is not coextensive with a search of Invention IV and V and it would be a tremendous burden to search all the groups without restriction. Should applicants traverse on the ground that Inventions I-III are not patentably distinct from Invention IV and V, applicants should submit evidence or identify such evidence now or record showing compounds of groups I-III are obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in an obviousness rejection under 35 USC §103(a).

Group VII is related to Groups I-III in that Groups VII requires a compound of Groups I-III to study a biological system or sample. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using theat product. See MPEP 806.05(h). In the instant case, the method can be practices with a materially different product. For example, U.S. Patent No. 4,299,813 describes a method and kit for determining levels of tricyclic antidepressants in body fulid, the method including the

step of measuring inhibition of the binding of radioactive muscarinic receptor binders disclosed therein.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP §821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is *presented prior to* final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai; In re Brouwer and 35 U.S.C. §103(b)," 1184 O.G. 86 (March 26, 1996).

Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. *Applicants are reminded of propriety of process of use claims in consideration of the "reach-through" format, which is drawn to mechanistic, receptor binding or enzymatic functionality. Reach-through claims are considered lacking of descriptive and enabling support from the specification. Thus, rejoinable process of use claims are those with particular disease named with efficacy support from the specification for treating the particular disease.* **Failure to do so may result in a loss of the right to rejoinder**.

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicants are advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed. See 37 CFR 1.143.

Applicant is reminded that upon the cancellation of claims to non-elected inventions, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to R. James Balls whose telephone number is (571) 272-7997. The examiner can normally be reached on Mon - Fri 8:00am - 4:30pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tom McKenzie can be reached on (571) 272-0670. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

R. James Balls
September 18, 2006

Celia Chang
Primary Examiner
Art Unit 1625